

Routine use of cell salvage during cesarean section: A practice evaluation

Charlotte Leeson¹  | Molly Jones¹ | Joshua Odendaal^{1,2} | Falguni Choksey² | Siobhan Quenby^{1,2}

¹Division of Biomedical Sciences, Clinical Sciences Research Laboratories, Warwick Medical School, University of Warwick, Coventry, UK

²University Hospitals Coventry & Warwickshire, Coventry, UK

Correspondence

Charlotte Leeson, Division of Biomedical Sciences, Clinical Sciences Research Laboratories, Warwick Medical School, University of Warwick, Coventry CV2 2DX, UK.

Email: charlotte.leeson@warwick.ac.uk

Abstract

Introduction: Intraoperative cell salvage is a well-documented alternative to donor blood transfusion given the scarcity of donor blood pools and the incumbent risk of allogenic blood transfusion. Its use in obstetrics has been limited by concern over fetal alloimmunization due to the risk of fetomaternal hemorrhage. However, there are a paucity of studies reporting on outcome. The aim of this study was to report on a four-year experience of routine use of intraoperative cell salvage and the impact on subsequent pregnancy outcomes.

Material and methods: This was a tertiary center retrospective service evaluation cohort study and included all women undergoing cesarean section between December 2014 and November 2018 in a tertiary obstetric unit, identifying women who had reinfusion of intraoperative cell salvage. Data regarding index pregnancy as well as subsequent pregnancies at the hospital were extracted from hospital electronic records. Subsequent pregnancy outcome and maternal antibody status in that pregnancy were collected up until November 2022.

Results: During the study period, 6656 cesarean sections were performed, with 436 (6.6%) receiving reinfusion of salvaged blood. The mean volume of reinfused blood was 396 mL. A total of 49 (0.7%) women received donor blood transfusion. Of those who received reinfusion of salvaged blood, 79 (18.1%) women had subsequent pregnancies over the eight-year follow-up period. There was one case (0.23%) of fetal cell alloimmunization demonstrated by the presence of anti-D antibodies on the subsequent pregnancy booking bloods.

Conclusions: Routine intraoperative cell salvage may be used to reduce the need for blood transfusion during cesarean section. The risk of fetal cell alloimmunization in a future pregnancy following reinfusion of intraoperative cell salvage is one in 436. Given an apparent small risk of fetal cell alloimmunization, further work is required to establish the safety profile of intraoperative cell salvage in pregnancy.

Abbreviations: CS, cesarean section; IOCS, intraoperative cell salvage; PPH, postpartum hemorrhage.

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KEYWORDS

allogeneic blood transfusion, fetal alloimmunization, intraoperative cell salvage, postpartum hemorrhage, pregnancy outcome

1 | INTRODUCTION

Hemorrhage remains a leading cause of maternal death and therefore optimal management is integral to good obstetric care.¹ If excessive blood is lost during cesarean section (CS), there are significant risks including the risk of requiring a hysterectomy, the development of disseminated intravascular coagulation or need for intensive care unit admission. There are well recognized risk factors for postpartum hemorrhage (PPH) which can be taken into consideration prior to a CS; however, rapid unexpected bleeding can occur. The rate of maternal death from hemorrhage between 2019 and 2021 was 0.82 per 100 000 maternities.¹

Blood transfusion is often used to treat major hemorrhage in obstetrics with complications of treatment rare.² However, it is not without risk. ABO mismatch and blood borne infections may still complicate transfusion and donor blood remains a scarce resource. A woman may also choose to decline blood transfusion.³

An alternative to donor blood transfusion is intraoperative cell salvage (IOCS) with autologous blood transfusion.⁴ This involves the collection, washing and reinfusion of blood lost at the time of the procedure.⁵ The benefits include the ability to return blood quickly to the patient and improved acceptability in patient groups that commonly decline donor blood transfusion.⁶

During the process of cell salvage, both maternal and fetal red blood cells are collected and returned to the mother as they cannot be distinguished from each other by the cell salvage equipment.⁷ Although it has been shown that this does not increase the volume of fetal cells in the maternal circulation in comparison to transfer in a normal pregnancy,⁸ a theoretical increased risk of fetal cell alloimmunization exists. Alloimmunization occurs when exposure to red cell antigens during the puerperium causes the formation of antibodies which could cause problems in future pregnancies. This encompasses not only the formation of anti-D, which is treated for prophylactically in rhesus negative pregnant women, but also more rare antibodies such as anti-K and anti-c.⁸

Another perceived risk of cell salvage is that of amniotic fluid embolism.⁹ Although rare, it has a very high mortality rate.¹⁰

The majority of units in the UK currently use a risk assessment for PPH to determine if cell salvage collection is used at the time of CS, taking into account factors such as placenta previa, placenta accreta or if the patient has a rare blood group which may delay cross-matching for donor blood transfusion.¹¹ However, it is reported that 60% of women who have a PPH did not have a pre-existing risk factor.¹² This suggests that many women could benefit from the routine use of IOCS.

The SALVO trial is the largest study to date on the use of routine IOCS; however, it did not investigate safety outcomes, in particular evidence on alloimmunization following autotransfusion.¹³ The trial

Key message

Routine use of intraoperative cell salvage at cesarean section is viable and reduces the need for blood transfusion. It carries a small risk of fetal cell alloimmunization and further work is required to establish the full safety implications on future pregnancies.

concluded that routine IOCS was not cost effective; however, it integrated confounding costs associated with PPH into the analysis.

This retrospective service evaluation cohort study evaluated the routine use of IOCS in a tertiary obstetric center over 4 years. It examined the rates of isoimmunization in subsequent pregnancies as well as maternal and fetal complications over an 8 year follow-up period.

2 | MATERIAL AND METHODS

All women undergoing CS between 01 December 2014 and 31 November 2018 were included in the study. Data held on a maternity information system were used to identify those delivered by CS and data was collected retrospectively. Due to the routine use of IOCS, all women who had a CS during the data collection period were included.

Women planned for CS undergoing vaginal or instrumental delivery on transfer to theater were excluded.

The cell salvage machine used was a SORIN XTRA (LivaNova, London, UK), and was operated in line with the manufacturer's instructions. The decision to process the blood for reinfusion is a joint decision made by the theater team when the estimated blood in the reservoir is >1000 mL, in accordance with the Royal College of Obstetrics and Gynecology guidelines on PPH.^{11,14} Reinfusion takes place using a standard blood giving protocol. Data is recorded onto a rolling IOCS dataset for all cases where cell salvage is set up. Data collected includes date of reinfusion, estimated blood in reservoir, reinfusion volume, hematocrit and total estimated blood loss at delivery. This data is stored electronically. If the blood is processed but not reinfused, the reasons for this are documented on the dataset. Adverse events, such as amniotic fluid embolism, allergic or transfusion-related reaction, are captured onto the rolling IOCS dataset and reported in line with the hospital policy on incident reporting.

Women who received reinfusion of salvaged blood were identified retrospectively from the IOCS dataset. The following data was extracted: date of reinfusion, estimated blood in reservoir,

reinfusion volume, hematocrit and total estimated blood loss at index delivery.

Details on donor blood usage in the reinfused cohort was generated from local blood track software. Blood product usage was recorded within 3 days of delivery.

Women undergoing a pregnancy subsequent to index cell salvage reinfusion were identified through the maternity information system. Any subsequent pregnancy up to November 1, 2022 was included within the study. Data collected included date of pregnancy, rhesus status, presence of antibodies at booking, booking hemoglobin levels, antenatal complications, gestation at delivery, mechanism of onset of labor, mode of delivery, estimated blood loss, pre- and post-delivery hemoglobin levels and neonatal outcome. Maternal group and antibody status at registration of the subsequent pregnancy were reviewed and compared to those at index delivery to establish new onset development of antibodies.

2.1 | Statistical analyses

Statistical analyses including descriptive statistics were carried out using SPSS (IBM SPSS Statistics for Macintosh, version 26.0. Armonk, NY: IBM Corp), and a significance threshold of $p < 0.05$ was used. To convert the reinfusion volume into packed red cell units, 300 mL was used as one unit of packed red blood cells.¹⁵

Shapiro–Wilk tests were used to assess normality. This suggested that estimated blood collected in reservoir, reinfused volume, hematocrit of processed blood and total estimated blood loss at index delivery were not normally distributed ($p < 0.05$). Mann–Whitney U test was used to investigate whether there was a significant difference in blood volumes between individuals having reinfusion of salvaged blood only compared to those having reinfusion of salvaged blood and additional donor blood.

The study is reported in line with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement.¹⁶

3 | RESULTS

Between December 2014–November 2018, 6656 CS were performed at our center. IOCS was routinely set up for all cases. A flow chart of eligible women can be seen in [Figure 1](#).

3.1 | Intraoperative cell salvage at index delivery

Of these women, 436 (6.6%) received reinfusion of salvaged blood at index delivery. [Table 1](#) shows cell salvage reinfusion data at index delivery. In total, 173 070 mL of salvaged blood was reinfused over a four-year period, equivalent to 577 units of packed red cells, which equates to an average of 1.32 units per patient undergoing reinfusion. No amniotic fluid embolisms secondary to reinfusion were reported.

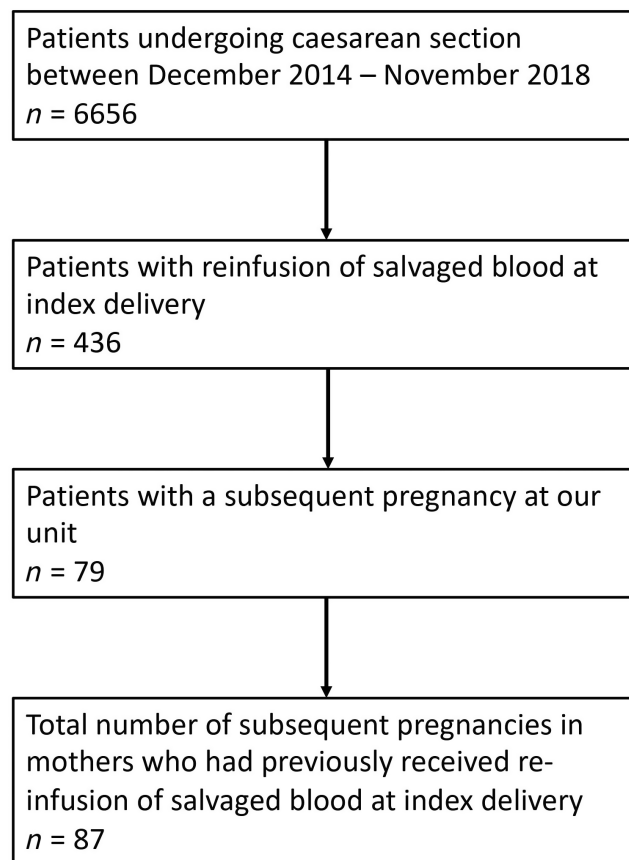


FIGURE 1 Number of women eligible for inclusion in the study, those who received reinfusion and number who went on to have a subsequent pregnancy.

TABLE 1 Reinfusion data at index delivery ($n = 436$).

Variable	
Estimated blood collected in reservoir (mL) ^a	1074 mL \pm 46 mL
Reinfused volume (mL)	397 mL \pm 15 mL
Hematocrit of processed blood (%) ^b	45 \pm 0.3
Total estimated blood loss at index delivery (mL) ^c	1450 mL \pm 46 mL

Note: All values represent mean and standard error of mean.

^aFor estimated blood collected in reservoir seven patients had missing data ($n = 429$).

^bFor hematocrit of processed blood 18 patients had missing data ($n = 418$).

^cFor total estimated blood loss at index delivery seven patients had missing data ($n = 429$).

3.2 | Donor blood products at index delivery

A total of 49 (0.7%) women required donor blood products perioperatively ([Table 2](#)). Of these 49 women, 26 had a sufficiently severe obstetric hemorrhage to require donor clotting factor infusion, seven had concurrent platelets infused and one platelets alone. This

Year* n = C sections	2015 n = 1541	2016 n = 1612	2017 n = 1730	2018 n = 1652
Number of women having salvaged blood infused	82	51	168	126
Number of reinfused women having donor RBC reinfusion	11	2	15	21
Total RBC units reinfused	35	6	37	92
Number of reinfused women having fresh frozen plasma reinfused	4	1	8	13
Total units of fresh frozen plasma reinfused	18	10	24	70
Number of reinfused women having cryoprecipitate	0	1	0	4
Total units of cryoprecipitate reinfused	0	4	0	7
Number of reinfused women having platelet transfusion	0	1	3	4
Total units of platelets transfused	0	6	4	6

TABLE 2 Transfusion of blood products at index delivery.

Abbreviation: RBC, red blood cells.

*For 2014 1 month (December) was included. In 2018 11 months were included (January–November). 2014 is not included in the table as no donor blood products were used.

TABLE 3 Comparison of blood volumes for patients who received reinfusion of salvaged blood compared to patients who received reinfusion of salvaged blood as well as donor blood products.

	Patients who had reinfusion of salvaged blood only at index delivery (n = 387) ^a	Patients who had reinfusion of salvaged blood and donor blood products at index delivery (n = 49) ^a	p-value
Total estimated blood lost at index delivery (mL) ^b	1273 ± 27	2887 ± 282	p = 0.000
Reinfused volume (mL)	349 ± 8	776 ± 99	p = 0.000
Hematocrit of processed blood (%) ^c	44 ± 0.3	45 ± 1.00	p = 0.138
Estimated blood in reservoir (mL) ^d	978 ± 40	1867 ± 239	p = 0.000

^aValues represent mean ± standard error of the mean.

^bFor estimated blood lost at index delivery seven patients had missing data.

^cFor hematocrit, 18 patients had missing data.

^dFor estimated blood in reservoir, seven patients had missing data.

meant only 22 (0.3%) had inadequate red cell salvage and required additional donor red cell infusion (Table 2). There were no trends in blood product use over time (Table 2).

The total estimated blood loss at index delivery, reinfusion volume and estimated blood in reservoir was significantly higher for women who had reinfusion of salvaged blood and additional donor blood products compared to those who had reinfusion of salvaged blood only ($p < 0.05$) for all variables (Table 3).

3.3 | Characteristics at subsequent pregnancy

A total of 79 women went on to have a total of 87 subsequent pregnancies at our center. Seven pregnancies resulted in miscarriage after the booking bloods, none of which had any antibodies present on their antenatal screen for their subsequent pregnancy. Two women were pregnant and had not yet delivered at the time

of final data collection. All pregnancies except one were singleton pregnancies, with the other being dichorionic diamniotic twins who were delivered at 29 + 0 weeks by emergency CS following preterm prelabor rupture of membranes. Mean booking hemoglobin was 122 (range 102–146 g/dL) and mean gestation at delivery was 37 weeks and 6 days. A total of 85% of women underwent a CS for their subsequent delivery (Table S1).

3.4 | Safety profile of IOCS

Seven women that had a subsequent pregnancy at our center had received donor blood products at index delivery. One patient was noted to have anti-E, anti-JKA and a nonspecific antibody on booking for subsequent pregnancy; however, on review of clinical notes, these were present before the index pregnancy, therefore, IOCS cannot be deemed as the cause.

There was one episode of fetal cell alloimmunization following reinfusion of salvaged blood identified in the next pregnancy. No other identifiable risk factors for this were established. This patient did not receive donor blood products at index delivery, excluding donor blood donation as a potential cause for alloimmunization. Prophylactic anti-D and nonspecific antibodies were detected on the initial pregnancy booking bloods. The initial anti-D titer was 9.2 IU/mL. The baby was born alive and well at 36 weeks gestation after a preterm CS due to increased middle cerebral artery blood flow.

No antenatal or neonatal complications known to be associated with antibody production for example, hydrops fetalis, were reported in any subsequent pregnancies.

4 | DISCUSSION

In this study, routine use of IOCS has been demonstrated to have the potential to reduce the need for blood transfusion during CS. IOCS is used efficiently and successfully at this tertiary unit, with reinfusion being used regularly during both elective and emergency procedures. We recognize the risk of fetal cell alloimmunization and present an example of this occurring within our study cohort. With one case identified of the 436 who received reinfusion, the risk remains small.

The uptake of IOCS in obstetrics is low due to clinician fear surrounding perceived risks to subsequent pregnancies, created by the presence of fetal cells and amniotic fluid.⁴ The primary risk factors for fetal alloimmunization remain previous pregnancy and blood transfusion.¹⁷ A large multinational study investigated all cases of hemolytic disease of the fetus and newborn (HDFN) as a result of alloimmunization, concluding that 83% of cases were due to previous pregnancy and 3% as a result of previous transfusion.¹⁷ Secondary risk factors include procedures which increase the chance of fetomaternal hemorrhage such as amniocentesis or chorionic villus sampling.¹⁸ The overall prevalence of clinically relevant alloantibodies in a prospective cohort study conducted in the Netherlands was 1:300 with a 1:500 risk of antibodies at significant levels to cause HDFN.¹⁹ The evidence suggests that up to 5% of those undergoing blood transfusion may present with alloantibody formation.²⁰ In comparison with this study, we suggest IOCS to be associated with a lesser risk of alloimmunization than standard blood transfusion.

To our knowledge, this is the only study to have investigated the safety of IOCS with regard to outcomes at subsequent pregnancy. We had no serious unexpected adverse reaction to the donor transfusion. The 49 women who did require donor blood products were those with significantly larger perioperative hemorrhages and included the 27 whose hemorrhage was so severe that clotting factors and/or platelets were required. Although we report no cases of amniotic fluid embolism within this study, the rarity of the condition means we cannot draw definite conclusions regarding its incidence.

Our follow up in subsequent pregnancy found a single episode of fetal cell alloimmunization. This case was managed well by the

local fetal medicine team and delivery was expedited at 36 weeks, with a good outcome for both mother and baby. Another patient was positive for anti-E, anti-JKA and a nonspecific antibody on blood tests prior to index delivery. Matching donor blood in women with unusual combinations of autoantibodies can be timely and difficult and IOCS is a viable option that can avoid this. In the previously published literature on IOCS during CS, there have been two identified cases of fetal cell alloimmunization. The first was positive for anti-S in a patient who after 33 weeks' gestation suffered multiple antenatal bleeds and had a significant placental abruption leading to CS. The authors concluded that the production of anti-S was more likely due to antenatal hemorrhage; however, they could not exclude IOCS as a possible cause.²¹ The second was positive for anti-E, but again, authors were unable to determine if this was naturally occurring or due to IOCS.²² Quantifying the risk of alloimmunization is a useful tool in the counseling of women prior to CS. As obstetric practice often involves the use of IOCS, routine or not, we must provide patients with accurate risks for future pregnancies.

Leukocyte depletion filters are additional components that can be added when reinfusing salvaged blood, removing factors less than 40 μ M in diameter. There is conflicting evidence for the use of leukocyte depletion filters as, although they have the perceived potential to remove causes of amniotic fluid embolism (for example, alpha-fetoprotein and fetal cells), they have been reported to cause severe hypotension.²³⁻²⁶ Furthermore, leukocyte depletion filters have, in practice, not been demonstrated to remove fetal cells.^{27,28} Multiple hospitals including ours have decided to remove leukocyte depletion filters from practice due to reported risks.

Although IOCS is widely acceptable to the obstetric population, there are a small number of contraindications to be acknowledged. Hemostatic agents such as Gelfoam or PerClot cannot be used with IOCS, or collection must be completed prior to its use.²⁹ Irrigating solutions are also only to be used after collection is complete. Conditions which predispose to red cell fragility, such as sickle cell disease or thalassemia are also relative contraindications to IOCS.³⁰

Due to the long-term use of routine IOCS at this unit over the last 11 years, staff are confident and experienced in its use. They receive regular training and are able to set up reinfusion in a timely manner, which is integral during rapid blood loss. This experience may contribute to the small rate of transfusion of donor blood products seen within this cohort. This suggests that the introduction of routine use of IOCS at other large units is likely to lead to a reduction in the need for donor blood products. Minimizing the need for blood products may be an important consideration during times of mismatch between supply and demand, as demonstrated during the covid-19 pandemic.³¹

RCOG Green-Top Guideline no. 47³² advises the use of IOCS when the anticipated blood loss is enough to cause anemia or to exceed 20% of the estimated blood volume. Although there are well-established risk factors for blood loss, there are many cases of PPH which are not anticipated antenatally. This means there are a group of patients who have larger than expected losses, in whom

a blood transfusion could have been avoided if they were offered routine IOCS.

Although we were able to identify a case of fetal cell alloimmunization following reinfusion, we could not directly attribute the alloimmunization to the exposure to reinfusion of salvaged blood. Routine use of IOCS means that we did not have a comparable control cohort without the use of historical cases. A control cohort taken from prior to the introduction of routine IOCS at this unit would be 11 years old and due to constant changes in practice and patient demographics, this would not be a matched control group.

The retrospective nature of this study lends itself to the risk of certain biases. During the eight-year study period, there was a move from paper antenatal and postnatal note-taking to a computerized system. This in itself is a risk for measurement bias during data collection and although this was performed thoroughly and systematically, this cannot be completely eliminated.

Women having a CS are not the only obstetric patients at risk of PPH, and this study does not acknowledge those who had a PPH during vaginal delivery as cell salvage is not used in this context.

This data suggests a lower rate of blood transfusion (0.7%) required perioperatively during the routine use of IOCS compared to that of 2.5% demonstrated in the SALVO trial.^{8,33} SALVO also incorporated an additional staff member for preparation of the IOCS reinfusion equipment into their cost effectiveness analysis, which our unit does not require. The SALVO trial deemed IOCS as not cost effective. Although we did not perform a cost analysis as part of this study, we suggest that following the incorporation of IOCS into routine practice, the rate of donor blood transfusions would be significantly lower than that reported in SALVO and the cost-effectiveness modeling would be substantially changed in favor of IOCS. A previous study has also shown lower rates of IOCS reinfusion in elective procedures;³⁴ however, our study showed effective reinfusion during both emergency and elective CS.

The findings of this study suggest that further work is required to establish the safety of IOCS in pregnancy and the risk of fetal cell alloimmunization. Although a randomized controlled study design would allow the isolation of this effect, this would be difficult to achieve in light of the very low reported incidence rate. We support other authors recommending that a central database is created to allow an understanding of the risks of IOCS in obstetrics to subsequent fetal outcome.^{8,35}

5 | CONCLUSION

Routine use of IOCS may be a viable alternative to donor blood transfusion at CS and can reduce the need for transfusion. In the present study, the risk of fetal cell alloimmunization in a future pregnancy following reinfusion of IOCS is one in 436 (0.23%).

AUTHOR CONTRIBUTIONS

Joshua Odendaal, Falguni Choksey and Siobhan Quenby conceptualized the study. Molly Jones, Joshua Odendaal and

Siobhan Quenby gained appropriate permissions. Charlotte Leeson, Molly Jones, Joshua Odendaal and Falguni Choksey carried out data collection. Charlotte Leeson, Molly Jones and Joshua Odendaal performed data analysis. Charlotte Leeson, Molly Jones and Joshua Odendaal prepared a draft of the manuscript. All authors contributed to editing and approval of the final version of the manuscript.

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CONFLICT OF INTEREST STATEMENT

The authors report that there are no conflicts of interest to declare.

ETHICS STATEMENT

Local research and development approval was obtained from the Biomedical and Scientific Research Ethics Committee (BSREC) at The University of Warwick for this service evaluation on September 23, 2019 (BSREC-CDA-SSC2-2019-09). This was also approved at trust level as a service evaluation and updated for further data collection on April 28, 2022 (reference SE0199).

ORCID

Charlotte Leeson  <https://orcid.org/0000-0003-4735-2452>

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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